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Vitamins and Calcium Supplements (cont.)

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Vitamin D deficiency among the elderly is quite common in the United States. In a study of hospitalized patients in a general medical ward, vitamin D deficiency was detected in 57% of the patients. An estimated 50% of elderly women consume far less vitamin D in their diet than is recommended.

The Food and Nutrition Board of the Institute of Medicine recommended the following as an adequate vitamin D intake: 200 IU daily for people 19-50 years old; 400 IU daily for those 51-70 years old; and 600 IU daily for those 71 years and older. An average multivitamin tablet contains 400 IU of vitamin D. Therefore, taking a multivitamin a day should help provide the recommended amount of vitamin D.

What are some general guidelines from *MedicineNet.com* based on available data?

- Eat at least 5 servings of vegetables and fruits daily. Fruits and vegetables are high in fiber and are rich in vitamin C and other antioxidant vitamins. They also contain other antioxidants.
- Women in childbearing years should take a multivitamin that contains at least 400 micrograms of folic acid daily for the prevention of neural tube birth defects.
- Adults should take one multivitamin daily. One multivitamin a day is safe and inexpensive. The multivitamin should contain 400 micrograms of folic acid, approximately 2-3 mg of vitamin B6, 6-9 micrograms of vitamin B12, and 400 IU of vitamin D. The folic acid and the other B vitamins can help lower homocysteine. The vitamin D is one of the important factors in preventing osteoporosis.
- People with an inadequate amount of calcium in their diet should consider calcium supplements. Please see [Osteoporosis Prevention and Treatment Update](#) to help calculate the amount of calcium supplements one may need.
- Eat less cholesterol and saturated fats.
- Stop smoking cigarettes, control high blood pressure and diabetes, lose

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excess weight, and exercise regularly.

- Adults should check their blood cholesterol profile (LDL cholesterol, HDL cholesterol, and cholesterol/HDL ratio) to determine their risk of heart attacks. Some adults should also check the size of their LDL cholesterol and level of their Lp(a) cholesterol. In addition to diet and exercise, medications are available to improve unfavorable cholesterol profiles.
- Vitamin E (400 IU/day) is recommended for patients with small LDL cholesterol particles and elevated Lp(a) cholesterol to help decrease oxidation of these cholesterol particles. Vitamin E may also prevent prostate cancer.
- Patients with an early onset of atherosclerosis and heart attacks should check their blood levels of homocysteine. (Normal levels of blood homocysteine are 6- 10umol/liter for women and 8-12 umol/liter for men). Most doctors will treat homocysteine levels higher than 9- 10umol/liter. A doctor experienced in treating coronary heart disease should supervise the treatment of hyperhomocysteinemia. Treatment involves high doses of the B vitamins (1-5 mg/day of folic acid, 10mg/day of B6, and 0.4 mg/day of B12). Though uncommon, high levels of B6 consumption can cause nerve damage (peripheral neuropathy).

What is the toxicity of vitamins and what precautions should be taken?

While most vitamins are safe, some have known adverse effects and drug interactions such as the following:

- The long term safety and side effects of high doses of vitamin C (one or more grams per day) is unknown. While adverse side effects of vitamin C are rare, vitamin C in high doses may cause kidney stones or anemia due to blood cell destruction in patients with G 6PD (glucose 6-phosphate dehydrogenase) deficiency.
- Vitamin A can cause birth defects. Therefore, pregnant women and women of childbearing age who are not using contraception should avoid vitamin A doses above the RDA. In infants and children, vitamin A toxicity can cause headache, nausea, vomiting, dizziness, eyeball protrusion, double vision, and brain swelling.
- Vitamin D can be toxic in doses above 2000 IU/day. Vitamin D toxicity can lead to excessively high blood calcium levels, constipation, kidney failure, nausea, weakness, and kidney stones.
- Vitamin E in high doses can increase the blood-thinning action of Coumadin. Coumadin is a blood thinner used in preventing blood clot formation in the arteries, heart chambers, and veins. Excessive blood thinning by coumadin can lead to an increased risk of bleeding.
- High doses of vitamin B6 (pyridoxine) can cause severe sensory nerve damage. This nerve damage has been reported among women who took high quantities of this vitamin to relieve symptoms of PMS.

Table I - United States recommended daily allowances (US RDAs)

Vitamins	Infants	Children under 4	Adults and children older than 4	Pregnant and lactating women
Fat-soluble				
A	1,500 IU	2,500 IU	5,000 IU	8,000 IU
D	400 IU	400 IU	400 IU	400 IU
E	5 IU	10 IU	30 IU	30 IU
K			80 mcg	

Water-soluble				
C (Ascorbic acid)	35 mg	40 mg	60mg	60 mg
Thiamine	0.5 mg	0.7 mg	1.5 mg	1.7 mg
Riboflavin	0.6 mg	0.8 mg	1.7 mg	2.0 mg
Niacin	8 mg	9 mg	20 mg	20 mg
B6 (pyridoxine)	0.4 mg	0.7 mg	2 mg	2.5 mg
Folic Acid	100 mcg	200 mcg	400 mcg	800 mcg
B12	2 mcg	3 mcg	6 mcg	8 mcg
Other				
Calcium	0.6 g	0.8 g	1.0 g	1.3 g
Iron	15 mg	10 mg	18 mg	18 mg

Table II - Vitamin deficiency syndromes

The deficient vitamin	Syndrome	Symptoms/signs
A	Xerophthalmia	Dry skin, dry eyes, and blindness in advanced cases
D	osteomalacia	Weak and deformed bones
K	hypoprothrombinemia	Decreased blood clotting factors, leading to increased risk of bleeding
E		Anemia
C	scurvy	Weakened tissues and bleeding
Thiamin	beriberi	Brain, nerve, and heart damage
Niacin	pellagra	Skin inflammation, diarrhea, dementia, and nerve damage
Folic acid		Anemia
B12		Anemia, nerve damage, and dementia

Table III - Diseases and conditions that can cause vitamin deficiencies in the US

Alcoholics with poor nutrition can develop thiamin, niacin, and folic acid deficiency.
Patients lacking pancreatic digestive enzymes (usually due to chronic pancreas damage from alcohol abuse or cystic fibrosis) cannot digest and absorb fat. Consequently, they cannot absorb those vitamins (A, D, E, and K) that dissolve only in fat (fat-soluble vitamins).

Patients with small intestine disorders (such as celiac sprue) also cannot absorb fat and the fat-soluble vitamins A, D, E, and K.

Patients with pernicious anemia do not have the necessary protein in the stomach to absorb vitamin B12.

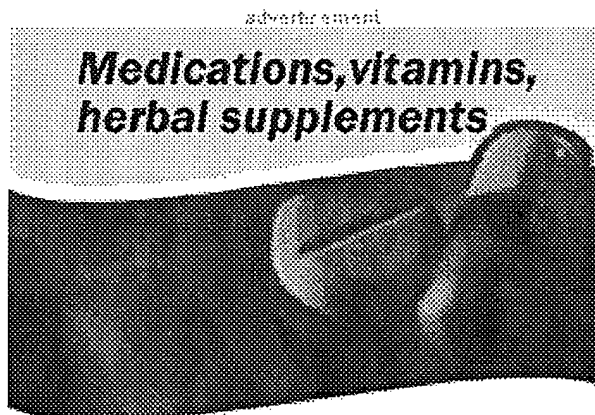
Patients with Crohn's disease involving the small intestine (Crohn's ileitis) or who have undergone small intestine resection may not be able to absorb vitamin B12.

Strict vegetarians who consume no animal products can develop B12 deficiency since there is a lack of B12 in vegetables.

Elderly individuals that are housebound can develop bone disease due to lack of vitamin D because of a combination of inadequate dietary intake and lack of sun exposure.

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Statements and information regarding dietary supplements have not been evaluated or approved by the Food and Drug Administration. Please consult your healthcare provider before beginning any course of supplementation or treatment.

L3 ANSWER 3 OF 6 CAPLUS COPYRIGHT 2005 ACS on STN

ACCESSION NUMBER: 1999:811042 CAPLUS
DOCUMENT NUMBER: 132:35185
TITLE: Dietary supplement for post-menopausal women
INVENTOR(S): Bell, Stacey J.; Bistrrian, Bruce R.; Forse, R. Armour
PATENT ASSIGNEE(S): Beth Israel Deaconess Medical Center, USA
SOURCE: PCT Int. Appl., 21 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 9965337	A1	19991223	WO 1999-US13676	19990616
W:	AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM			
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AU 9945738	A1	20000105	AU 1999-45738	19990616
PRIORITY APPLN. INFO.:			US 1998-100388	A 19980619
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REFERENCE COUNT: 4 THERE ARE 4 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

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PATENT ASSIGNEE(S): USA

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DOCUMENT NUMBER: 120:307495

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INVENTOR(S): Paradissis, George; Levinson, R. Saul; Heeter, Gary; Cuca, Robert; Kirschner, Mitchell I.

PATENT ASSIGNEE(S): KV Pharmaceutical Corp., USA

SOURCE: PCT Int. Appl., 57 pp.

CODEN: PIXXD2

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			WO 1993-US8926	W 19930921
			US 1995-410733	A1 19950327
			US 1996-604924	B3 19960222

AB Multi-vitamin and mineral supplements for administration to a pregnant women during her first, second, and third trimesters of pregnancy comprising specific regimens of a pharmaceutically acceptable **calcium compound, vitamin D, folic acid, vitamin B12, vitamin B6,** and vitamin B1. The prenatal supplements are specifically tailored to maximize fetal development and maternal health during each trimester of pregnancy. Tablets containing above vitamins and mineral supplements for administration during each trimester of pregnancy are prepared

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potentially detrimental change in the health of an individual. A condition "associated" with a hormonal change can be directly or indirectly caused by the hormonal change. Conditions associated with hormonal changes include, but are not limited to, ~~conditions associated with~~ menopause, hormone replacement therapy, ovariectomy/hysterectomy, cancer therapy, hot flashes, bone loss, high-risk pregnancy, osteoporosis, endometriosis, and uterine fibroids. "Treatment of" or "treating" a condition does not require elimination of the condition, i.e., curing of a disease.

does
not
say
what
the
condition
is

Accordingly, an "effective amount" of a vitamin composition is defined herein as an amount of the vitamin composition capable of preventing or reducing the severity or occurrence of one or more conditions in an individual. In some embodiments, a vitamin composition described herein is administered to an individual in an amount effective to reduce the occurrence or severity of hot flashes, bone loss, high-risk pregnancy, osteoporosis, endometriosis, or uterine fibroids. In other embodiments, a vitamin composition described herein is administered to an individual in an amount effective to prevent hot flashes, bone loss, high-risk pregnancy, osteoporosis, endometriosis, or uterine fibroids. The individual described herein may be any individual, and in some embodiments is a pre-menopausal, menopausal or post-menopausal female.

A vitamin composition may also be administered to an individual in an amount effective to treat or prevent one or more of the following conditions: hyperhomocystineamia, "in-situ" vascular free radical formation and hypertension. In a preferred embodiment of the present invention, the vitamin compositions of the present invention treat or prevent hyperhomocystineamia, bone loss, "in-situ" vascular free radical formation and hypertension. Bone loss may or may not amount to osteoporosis as clinically defined.

Hormonal changes may occur in an individual due to treatment of the individual with estrogen, androgen or estrogen-androgen combination therapies or other long-term steroid treatments. One non-limiting example of an estrogen-androgen combination is Estratest, an estrogen-testosterone combination for improving sexual function. Hormonal changes may also occur in an individual due to menopause, smoking, exercise, cancer chemotherapy or ovariectomy/hysterectomy. Such hormonal changes can increase the individual's risk of hot flashes, high-risk pregnancy, bone loss, osteoporosis, cardiovascular disease, and osteopenia. In

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intrapulmonary, intrarectal, intrarenal, intraretinal, intraspinal, intrasynovial, intrathoracic, intrauterine, intravesical, bolus, vaginal, rectal, buccal, sublingual, intranasal, iontophoretic means, and transdermal means. In a preferred embodiment, a vitamin composition is administered orally.

The following examples will serve to further illustrate the present invention without, at the same time, however, constituting any limitation thereof. On the contrary, it is to be clearly understood that resort may be had to various embodiments, modifications and equivalents thereof which, after reading the description herein, may suggest themselves to those skilled in the art without departing from the spirit of the invention.

EXAMPLE 1

Preparation of Vitamin Composition

A vitamin composition is prepared that comprises folic acid USP 1.6 mg, vitamin B12 (hydroxocobalamin) USP 500 mcg, vitamin B6 (pyridoxine) USP 25 mg, calcium USP (as carbonate) 400 mg, and vitamin D3 USP 400 IU. A vitamin formulation containing the vitamin composition further contains carnauba wax, citric acid, dicalcium phosphate, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, riboflavin, silicon dioxide, sodium benzoate, sodium citrate, sodium starch glycolate, sorbic acid, starch, stearic acid and titanium dioxide.

EXAMPLE 2

Administration of Vitamin Composition

The vitamin composition described in Example 1 is indicated for the distinctive nutritional requirements of: individuals with or at risk for cardiovascular disease, cerebrovascular disease, or osteoporosis, with particular emphasis on menopausal patients; patients treated with estrogen, androgen, estrogen-androgen combination therapies, or estrogen-progesterone combination therapies; smokers; patients with endometriosis or uterine fibroids; patients undergoing long term steroid treatments or cancer chemotherapy; and patients who have had a high-risk pregnancy, hysterectomy and or ovariectomy. Dosage and administration in adults is one to two tablets daily or as directed by a physician.


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Vitamins and Calcium Supplements (cont.)

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Vitamin D deficiency among the elderly is quite common in the United States. In a study of hospitalized patients in a general medical ward, vitamin D deficiency was detected in 57% of the patients. An estimated 50% of elderly women consume far less vitamin D in their diet than is recommended.

The Food and Nutrition Board of the Institute of Medicine recommended the following as an adequate vitamin D intake: 200 IU daily for people 19-50 years old; 400 IU daily for those 51-70 years old; and 600 IU daily for those 71 years and older. An average multivitamin tablet contains 400 IU of vitamin D. Therefore, taking a multivitamin a day should help provide the recommended amount of vitamin D.

What are some general guidelines from *MedicineNet.com* based on available data?

- Eat at least 5 servings of vegetables and fruits daily. Fruits and vegetables are high in fiber and are rich in vitamin C and other antioxidant vitamins. They also contain other antioxidants.
- Women in childbearing years should take a multivitamin that contains at least 400 micrograms of folic acid daily for the prevention of neural tube birth defects.
- Adults should take one multivitamin daily. One multivitamin a day is safe and inexpensive. The multivitamin should contain 400 micrograms of folic acid, approximately 2-3 mg of vitamin B6, 6-9 micrograms of vitamin B12, and 400 IU of vitamin D. The folic acid and the other B vitamins can help lower homocysteine. The vitamin D is one of the important factors in preventing osteoporosis.
- People with an inadequate amount of calcium in their diet should consider calcium supplements. Please see [Osteoporosis Prevention and Treatment Update](#) to help calculate the amount of calcium supplements one may need.
- Eat less cholesterol and saturated fats.
- Stop smoking cigarettes, control high blood pressure and diabetes, lose



excess weight, and exercise regularly.

- Adults should check their blood cholesterol profile (LDL cholesterol, HDL cholesterol, and cholesterol/HDL ratio) to determine their risk of heart attacks. Some adults should also check the size of their LDL cholesterol and level of their Lp(a) cholesterol. In addition to diet and exercise, medications are available to improve unfavorable cholesterol profiles.
- Vitamin E (400 IU/day) is recommended for patients with small LDL cholesterol particles and elevated Lp(a) cholesterol to help decrease oxidation of these cholesterol particles. Vitamin E may also prevent prostate cancer.
- Patients with an early onset of atherosclerosis and heart attacks should check their blood levels of homocysteine. (Normal levels of blood homocysteine are 6- 10umol/liter for women and 8-12 umol/liter for men). Most doctors will treat homocysteine levels higher than 9- 10umol/liter. A doctor experienced in treating coronary heart disease should supervise the treatment of hyperhomocysteinemia. Treatment involves high doses of the B vitamins (1-5 mg/day of folic acid, 10mg/day of B6, and 0.4 mg/day of B12). Though uncommon, high levels of B6 consumption can cause nerve damage (peripheral neuropathy).

What is the toxicity of vitamins and what precautions should be taken?

While most vitamins are safe, some have known adverse effects and drug interactions such as the following:

- The long term safety and side effects of high doses of vitamin C (one or more grams per day) is unknown. While adverse side effects of vitamin C are rare, vitamin C in high doses may cause kidney stones or anemia due to blood cell destruction in patients with G 6PD (glucose 6-phosphate dehydrogenase) deficiency.
- Vitamin A can cause birth defects. Therefore, pregnant women and women of childbearing age who are not using contraception should avoid vitamin A doses above the RDA. In infants and children, vitamin A toxicity can cause headache, nausea, vomiting, dizziness, eyeball protrusion, double vision, and brain swelling.
- Vitamin D can be toxic in doses above 2000 IU/day. Vitamin D toxicity can lead to excessively high blood calcium levels, constipation, kidney failure, nausea, weakness, and kidney stones.
- Vitamin E in high doses can increase the blood-thinning action of Coumadin. Coumadin is a blood thinner used in preventing blood clot formation in the arteries, heart chambers, and veins. Excessive blood thinning by coumadin can lead to an increased risk of bleeding.
- High doses of vitamin B6 (pyridoxine) can cause severe sensory nerve damage. This nerve damage has been reported among women who took high quantities of this vitamin to relieve symptoms of PMS.

Table I - United States recommended daily allowances (US RDAs)

Vitamins	Infants	Children under 4	Adults and children older than 4	Pregnant and lactating women
Fat-soluble				
A	1,500 IU	2,500 IU	5,000 IU	8,000 IU
D	400 IU	400 IU	400 IU	400 IU
E	5 IU	10 IU	30 IU	30 IU
K			80 mcg	

Water-soluble				
C (Ascorbic acid)	35 mg	40 mg	60mg	60 mg
Thiamine	0.5 mg	0.7 mg	1.5 mg	1.7 mg
Riboflavin	0.6 mg	0.8 mg	1.7 mg	2.0 mg
Niacin	8 mg	9 mg	20 mg	20 mg
B6 (pyridoxine)	0.4 mg	0.7 mg	2 mg	2.5 mg
Folic Acid	100 mcg	200 mcg	400 mcg	800 mcg
B12	2 mcg	3 mcg	6 mcg	8 mcg
Other				
Calcium	0.6 g	0.8 g	1.0 g	1.3 g
Iron	15 mg	10 mg	18 mg	18 mg

Table II - Vitamin deficiency syndromes

The deficient vitamin	Syndrome	Symptoms/signs
A	Xerophthalmia	Dry skin, dry eyes, and blindness in advanced cases
D	osteomalacia	Weak and deformed bones
K	hypoprothrombinemia	Decreased blood clotting factors, leading to increased risk of bleeding
E		Anemia
C	scurvy	Weakened tissues and bleeding
Thiamin	beriberi	Brain, nerve, and heart damage
Niacin	pellagra	Skin inflammation, diarrhea, dementia, and nerve damage
Folic acid		Anemia
B12		Anemia, nerve damage, and dementia

Table III - Diseases and conditions that can cause vitamin deficiencies in the US

Alcoholics with poor nutrition can develop thiamin, niacin, and folic acid deficiency.
Patients lacking pancreatic digestive enzymes (usually due to chronic pancreas damage from alcohol abuse or cystic fibrosis) cannot digest and absorb fat. Consequently, they cannot absorb those vitamins (A, D, E, and K) that dissolve only in fat (fat-soluble vitamins).

Patients with small intestine disorders (such as <u>celiac sprue</u>) also cannot absorb fat and the fat-soluble vitamins A, D, E, and K.
Patients with <u>pernicious anemia</u> do not have the necessary protein in the stomach to absorb vitamin B12.
Patients with <u>Crohn's disease</u> involving the small intestine (Crohn's ileitis) or who have undergone small intestine resection may not be able to absorb vitamin B12.
Strict vegetarians who consume no animal products can develop B12 deficiency since there is a lack of B12 in vegetables.
Elderly individuals that are housebound can develop bone disease due to lack of vitamin D because of a combination of inadequate dietary intake and lack of sun exposure.


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